K003128

AUG 1 2 2002

SECTION 9: 510(k) SUMMARY

Name and Address of Manufacturer:	The Joel Martin Kohn Company Suite #51 1424 Polk Street San Francisco, CA 94109
Contact:	Charles L. Morin Morin & Associates Regulatory Counsel (P) (415) 957-0101 (F) (415) 957-5905 email: charleslmorin@earthlink.net
Establishment Registration Number:	JMKC currently has no establishment registration number. Before manufacturing and commercializing the device here in question JMKC will file for and obtain the requisite number.
Common and Proprietary Names:	**Common names:** Truncal orthosis devices, Pressure applying devices, and Physical medicine devices **Proprietary name:** RELIEFBRIEF
Device Class:	Class I
Classification Name:	Truncal orthosis devices (21 CFR Section 890.3490)
Performance Standards:	No pertinent standards

Device description:

The RELIEFBRIEF resembles a cotton lycra panty girdle with two Velcro-lined stretch pockets (one in the front and one in the rear) that contain 1-1/2 inch hemispheric latex foam rubber pads (i.e., acupads) which apply pressure against specific dysmenorrhea-relieving Chinese acupressure points. The two stretch pockets sewn into the garment hold each latex foam acupad in place over specific acupressure points. Pressure against the abdomen and the lower back is exerted through the use of an attached elastic belt which can be adjusted so that the resulting pressure is as tight as is comfortable.

Intended use:

The RELIEFBRIEF is indicated for use as a lumbo-sacral support and as an acupressure device for the purpose of reducing menstrual pain symptoms (including cramps, abdominal pain, and backache) and reducing pain medication use associated with menstruation.

Safety and effectiveness:

In order to assure that JMKC's RELIEFBRIEF performs as intended and is safe and effective for the additional intended use here at issue, i.e., as an acupressure device for the management of pain symptoms and pain medication use associated

with dysmenorrhea, JMKC sponsored -- via a grant from NIH -- a clinical trial at UCSF General Clinical Research Center. The general purpose of this clinical trial was to develop and test the safety and effectiveness of a proprietary acupressure garment (i.e., the RELIEFBRIEF) in decreasing the pain and pain medication use associated with dysmenorrhea. More specifically, the aims of the clinical trial, with women who experienced moderate-to-severe dysmenorrhea, were 1.) to determine the effectiveness of the RELIEFBRIEF in reducing the severity of menstrual pain, reducing menstrual symptom severity, and decreasing pain medication use, and 2.) to determine the ease of use and any adverse effects associated with wearing the RELIEFBRIEF.

With regard to such clinical trial and in summary, 61 women with primary dysmenorrhea were randomized to a control group or an experimental acupressure device (i.e., the RELIEFBRIEF) group after one pre-treatment menses, with 58 women reporting the effect on their pain during two subsequent menstrual cycles. Moderately severe cramps, abdominal pain and backache reported by all women at the pre-treatment baseline menstrual cycle declined in intensity for women wearing the RELIEFBRIEF during the first treatment cycle and the lower menstrual pain levels were maintained during the second treatment cycle compared to the Control group. Sixty one percent of the women wearing the RELIEFBRIEF demonstrated at least a 25% reduction in menstrual pain severity and 41% had more than a 50% reduction in pain symptom intensity. The use of pain medications decreased in the group who wore the acupressure device compared to the control group. There were no adverse side effects noted from wearing the RELIEFBRIEF. Consequently, the investigations concluded that the RELIEFBRIEF is an effective and safe non-pharmaceutical strategy for the treatment of primary dysmenorrhea in some women.

Further, they concluded that the RELIEFBRIEF could serve as a main treatment modality for women who suffer from primary dysmenorrhea and do not wish to or cannot use the conventional pharmacological agents. Finally, they concluded that the RELIEFBRIEF could serve as an adjuvant therapy to medication in more severe cases of dysmenorrhea.

Please note that the investigators also noted that a majority of the women found that the RELIEFBRIEF was inconvenient to wear and that these inconveniences limited the duration of use. Consequently, they recommended some design modifications which changes have been incorporated into the current product design.

Substantial equivalence:

JMKC's RELIEFBRIEF is clearly a physical medical device. (See 21 CFR Part 890). And it was found to be so when first cleared for its initial intended use, i.e., as a truncal orthosis device. (See K935574; and 21 CFR Section 890.3490). Even with the addition of the additional intended use here in question, i.e., as an acupressure device for the management of pain symptoms and pain medication use associated with dysmenhorrhea, JMKC believes such device remains a physical medical device operating substantially equivalently to JMKC's prior cleared RELIEFBRIEF in that both provide support – in the form of pressure – to a portion of the trunk of the body.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 12 2002

The JM Kohn Company
C/O Charles L. Morin
Morin & Krasny, LLP
201 Spear Street, Suite 1600
San Francisco, California 94105-1635

Re: K003128
Trade/Device Name: The Relief Brief®
Regulation Number: 21 CFR 890.3490
Regulation Name: Orthosis, Truncal for Dysmenorrhea
Regulatory Class: I
Product Code: NJB
Dated: May 16, 2002
Received: May 17, 2002

Dear Mr. Morin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration

and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K003128

Device Name: The RELIEFBRIEF®

Indications for Use:

The RELIEFBRIEF® resembles a panty girdle and has been specifically designed and is intended to provide pressure to various acupressure points (on the lower abdomen and lower back) for the purpose of reducing menstrual pain symptoms (including cramps, abdominal pain, and backache) and reducing pain medication use associated with menstruation.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Patricia Cucente

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K003128

(Optional Format 3-10-98)

Posted July 1, 1998)